

- Diego, California, Court of Federal Claims No: 20–1439V
109. Richard Dennis Miszewski, West Allis, Wisconsin, Court of Federal Claims No: 20–1440V
110. Raiza Halpert and Moshe Halpert on behalf of J.H., Monroe, New York, Court of Federal Claims No: 20–1441V
111. Dominique Roberts, Albuquerque, New Mexico, Court of Federal Claims No: 20–1442V
112. Timothy Schwalbe, Milwaukee, Wisconsin, Court of Federal Claims No: 20–1445V
113. Jennifer Mire, Republic, Missouri, Court of Federal Claims No: 20–1449V
114. Douglas J. Hoos, Grand Island, Nebraska, Court of Federal Claims No: 20–1450V
115. Kathleen Runser, College Park, Maryland, Court of Federal Claims No: 20–1451V
116. Karen Valentine, Boston, Massachusetts, Court of Federal Claims No: 20–1453V
117. Peggy Lund, Minnetonka, Minnesota, Court of Federal Claims No: 20–1454V
118. Julia Hunt, Brooklyn, New York, Court of Federal Claims No: 20–1455V
119. Heather Hayes and Mark Hayes on behalf of A.H., Cincinnati, Ohio, Court of Federal Claims No: 20–1457V
120. Kathryn Becker, Boston, Massachusetts, Court of Federal Claims No: 20–1461V
121. Humberto Rodriguez, Stamford, Connecticut, Court of Federal Claims No: 20–1464V
122. Erma Lamb, Boston, Massachusetts, Court of Federal Claims No: 20–1465V
123. Jennifer Inscoe, Forest, Virginia, Court of Federal Claims No: 20–1466V
124. Paula DeBusk, Fayetteville, Arkansas, Court of Federal Claims No: 20–1470V
125. Nicole Fortney, Boston, Massachusetts, Court of Federal Claims No: 20–1471V
126. Michael Kochenderfer, Boston, Massachusetts, Court of Federal Claims No: 20–1472V
127. Julie Roubik on behalf of Estate of Thomas Roubik, Deceased, Holmen, Wisconsin, Court of Federal Claims No: 20–1473V
128. Debra Gadd, Sandusky, Ohio, Court of Federal Claims No: 20–1474V
129. Michael Mendoza on behalf of Christian Mendoza, Chino, California, Court of Federal Claims No: 20–1475V
130. Dianne Byrd, Albuquerque, New Mexico, Court of Federal Claims No: 20–1476V
131. Krista Wall, Encinitas, California, Court of Federal Claims No: 20–1477V
132. Grace Shain on behalf of H.S., Phoenix, Arizona, Court of Federal Claims No: 20–1478V
133. Angela Butts, Washington, District of Columbia, Court of Federal Claims No: 20–1479V
134. Melissa Manie, Moberly, Missouri, Court of Federal Claims No: 20–1482V
135. Carmen C. Salas, San Juan, Puerto Rico, Court of Federal Claims No: 20–1483V
136. Mitzi Lee, Richmond, Virginia, Court of Federal Claims No: 20–1484V
137. Kathryn DeLeon on behalf of N.C., Boston, Massachusetts, Court of Federal Claims No: 20–1485V
138. John Michael Dulaney, Boerne, Texas, Court of Federal Claims No: 20–1488V
139. Peggy McCarter, Greensboro, North Carolina, Court of Federal Claims No: 20–1490V
140. Francine Russo, Athens, Georgia, Court of Federal Claims No: 20–1491V
141. Kelli Wilson, Caldwell, Idaho, Court of Federal Claims No: 20–1492V
142. Melissa Greenberg and Richard Greenberg on behalf of M.G., Boston, Massachusetts, Court of Federal Claims No: 20–1493V
143. Nina Cupples, Rutherford, Tennessee, Court of Federal Claims No: 20–1494V
144. Rodney Burrill, Seattle, Washington, Court of Federal Claims No: 20–1495V
145. Veronica Williams, Dallas, Texas, Court of Federal Claims No: 20–1499V
146. Maria Ramos, The Woodlands, Texas, Court of Federal Claims No: 20–1500V
147. Audrey Chinnock, Overland Park, Kansas, Court of Federal Claims No: 20–1501V
148. Regina Mileouski, Dresher, Pennsylvania, Court of Federal Claims No: 20–1502V
149. Luis Rodriguez, Richmond, Virginia, Court of Federal Claims No: 20–1503V
150. Debra S. Colgan, White Plains, New York, Court of Federal Claims No: 20–1505V
151. Kathleen Finn, Boston, Massachusetts, Court of Federal Claims No: 20–1506V

[FR Doc. 2020–25287 Filed 11–16–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Request for Information—Landscape Analysis To Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations**

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The Office of the Assistant Secretary for Health (OASH) in the Department of Health and Human Services, in partnership with other federal agencies, seeks to gain a more comprehensive understanding from health systems, community based organizations, academic institutions, non-federal government agencies, innovators, entrepreneurs, non-profit organizations, and other relevant stakeholders regarding innovative solutions to chronic disease management leveraging novel technologies (*e.g.*, artificial intelligence (AI), biosensors, apps, remote monitoring, 5G) to optimize compliance with evidence-based standards of care in disease states that cause significant morbidity and mortality in aging populations in underserved areas (*e.g.*, low income, Medicaid-eligible, rural). OASH will review information collected in this request for information (RFI) to better inform federal government priorities and programs. We also seek to identify opportunities to strengthen the U.S. healthcare system, as a whole, through public-private partnerships in data sharing, comprehensive analytics including AI, and other potential mechanisms. OASH welcomes public feedback related to how these questions should be addressed and/or potential solutions. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be assured consideration, comments must be received at the email address provided below, no later than midnight Eastern Time (ET) on December 22, 2020.

ADDRESSES: Individuals are encouraged to submit responses electronically to OASHcomments@hhs.gov. Please indicate “RFI RESPONSE” in the subject line of your email. Submissions received after the deadline will not be reviewed. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant. Respond concisely and in plain language. You may use any structure or layout that

presents your information well. You may respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also include links to online material or interactive presentations. Clearly mark any proprietary information, and place it in its own section or file. Your response will become government property, and we may publish some of its non-proprietary content.

FOR FURTHER INFORMATION CONTACT: Dr. Leith States, Chief Medical Officer, Office of the Assistant Secretary for Health, (202) 260–2873.

SUPPLEMENTARY INFORMATION:

Background

The Office of the Assistant Secretary for Health—in partnership with Division of Cardiovascular Sciences, National Heart, Lung, and Blood Institute, National Institutes of Health; Administration for Community Living; Agency for Healthcare Quality and Research; United States Department of Agriculture; Federal Communications Commission; and the White House Office of Science and Technology Policy—is interested in resources that enhance quality of life for aging populations by enabling access to emerging technologies and access to healthcare services. The COVID–19 response has disrupted access to routine and emergency healthcare services in many, if not most, communities. It is estimated that 41 percent of U.S. adults delayed or avoided medical care due to concerns over COVID–19 transmission.¹ At the same time, the pandemic resulted in a strain on the country's public health and healthcare infrastructure. The populations affected most by this pandemic are those that experienced inequities in healthcare at baseline. These inequities are widely understood to be driven in part by upstream predictors identified as the social determinants of health (SDOH)—conditions in the environment in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.²

Related to these social risk factors, the biological risk factors most closely associated with increased risk for COVID–19 include age (65 years and older) and chronic diseases (e.g., cancer, chronic kidney disease, Alzheimer's disease and related dementias, chronic obstructive pulmonary disease, heart

disease and stroke, diabetes, and obesity). Underscoring the vulnerability of older adults, the highest rates of hospitalization and death from COVID–19 are in the older adult population. In fact, eight in ten COVID–19-related deaths reported in the United States have been among adults 65 and older.³ This situation is exacerbated in rural communities, for example which, compared to urban areas, are characterized by a higher percentage of older adults, higher rates of all-cause mortality, and lower density of healthcare infrastructure.^{4,5} The pandemic's further exacerbation of inequities in healthcare delivery introduces the opportunity to identify, develop, deploy and evaluate innovative technological approaches to chronic disease management, as well as the opportunity to mitigate any introduction of biases that could increase disparities in healthcare when applying such innovative approaches. Technological advances (e.g., artificial intelligence (AI) driven solutions) have great potential to improve health outcomes in the aging population, particularly for those in underserved areas (e.g., low income, Medicaid-eligible, rural) by empowering patients and facilitating integrated healthcare delivery.

Leveraging data and applying technologies to improve health for aging populations in underserved areas is of interest. These include, for example, advancing data availability from health systems (e.g., claims data, electronic health records, surveillance data, etc.), applying AI to inform behavior change through remote patient monitoring, and assessing risk to then apply appropriate preventive/acute care—all to mitigate excess morbidity and mortality from chronic diseases. The federal government has taken some action to demonstrate this interest. For example, the Collaborative Aging (in Place) Research Using Technology (CART) project, a joint effort between the Veterans Health Administration and the National Institutes of Health, was launched to support future applications of AI and machine learning to improve health and healthcare delivery through systematic evaluation of technologies that enable older adults to remain independent. These efforts align with

the National Artificial Intelligence Research and Development Strategic Plan, an interagency product released in 2019, which lays out eight strategic priority areas for federal investment in AI research and development. The utility of these technologies requires access to patient monitoring technologies and the data infrastructure to support analytics and transmission to integrated care teams (e.g., primary care, subspecialty care, nursing, pharmacy, social work, assisted living providers) that can effectively leverage signals that emerge within this system. To better inform the direction of federal efforts, OASH and its partners seek information about complementary technological activities by identifying common themes (e.g., barriers, opportunities, gaps), highlighting innovative solutions to chronic disease management, and enhancing the potential for joint public-private activities to serve aging populations in underserved areas focusing on the imperative to understand and capitalize on opportunities to develop, operationalize, and scale innovations in healthcare and delivery at the individual and population levels for aging Americans.

Scope and Assumptions

- The purpose of this RFI is to gain a more comprehensive understanding of how health systems, community based organizations, academic institutions, non-federal government agencies, innovators, entrepreneurs, non-profit organizations, industry and other relevant stakeholders are approaching innovative efforts around chronic disease management (e.g., heart failure, hypertension, chronic lower respiratory disorders, cognitive impairment) for aging populations in underserved areas (e.g., rural) by leveraging technology-driven solutions (e.g., AI), including those designed to optimally utilize future 5G infrastructure.

- Responses may span the continuum of care including but not limited to detection, prevention (e.g., falls risk reduction), education, lifestyle modification and behavior change (e.g., diet, exercise), treatment and rehabilitation of disease.

- We are interested in novel approaches and associated frameworks for collecting data confirming efficacy and/or effectiveness of technology solutions with demonstrated improvements in one or more of the following measures: Patient outcomes, access, safety, quality, cost, and value.

- If responses refer to proposed or ongoing projects, the following information should be included:

³ Available at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>.

⁴ Available at: https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/05/Snapshot2017.pdf.

⁵ Available at: https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/08/Regional-Differences-in-Urban-and-Rural-Mortality-Trends.pdf.

¹ Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6936a4.htm#T1_down.

² Available at: <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>.

Description, rationale, study design, data sources (to include harmonization/cleaning of data), funding organization(s), outcomes of interest, and how such an approach would avoid increasing disparities in care.

- Responses may include implications for scaling an intervention to broader population levels and other settings.

- The definition of “AI-driven solution”, for the purposes of this RFI, should be interpreted broadly. We seek an understanding of innovative activities across the spectrum of care in underserved settings for older adults.

- This RFI also seeks to identify opportunities to strengthen the U.S. healthcare system through public-private partnerships. The RFI seeks to identify organizations that would be interested in discussing the form and function of such collaborations.

Topics

A. Barriers and Opportunities for Technology-Driven Solutions

1. What barriers (e.g., privacy concerns, other clinician and patient barriers) and opportunities are most relevant for bringing technology-driven solutions to aging populations in underserved areas?

2. What federal policies currently limit the capacity to deploy and scale technology-driven solutions for aging populations?

3. What new federal policies could facilitate the success of technology-driven solutions for aging populations?

4. What are the ways in which technology-driven solutions are manifested (e.g., software platforms, wearables, robotics, etc.) and how is the integrity of data collected ensured (e.g., fidelity, and accuracy of data)?

5. How will training data sets be established and implemented to drive effective technology solutions that improve chronic disease outcomes for aging populations in rural areas?

6. How will AI solutions be validated? What metrics will be used to evaluate the effectiveness of AI/machine learning algorithms?

7. How will healthcare team and patient trust in technology solutions be addressed? How will legal and ethical issues be addressed for technology solutions designed for improving chronic disease outcomes?

8. How will bias and variance be addressed in machine learning algorithms for this application? How will supervised versus unsupervised learning be used to develop inferences and patterns from data sources? What will be the challenges and proposed

solutions for data cleansing and transformation?

9. Will AI deep learning and neural networks approaches and solutions be appropriate and used for chronic disease improvement for aging populations?

10. What are the per-person-costs of technology-driven solutions in the context of this RFI?

B. Key Indicators & Data Sources of Technology-Driven Chronic Disease Management

1. What key indicators or data sets will be used to perform measure outcomes (e.g., racial, ethnic, gender, and socioeconomic disparities)?

2. What existing methods, data sources, and analytic approaches are being used to assess and monitor technology-driven solutions (e.g., AI) in healthcare systems?

3. What selected health conditions should be addressed as priority conditions to assess technology-driven capacity to influence access, timeliness, and quality of healthcare treatment and preventive services to aging populations living in rural areas?

C. Examples of Health Promotion Using Technology-Driven Solutions

1. Describe novel technology-driven approaches (e.g., AI) that may prevent the onset, progression, or escalation of chronic disease states in patients who have decreased frequency of health system interaction during the COVID-19 pandemic, such as aging Americans living in rural areas.

2. Outline programs leveraging novel technology-driven approaches that may prevent increases in morbidity and mortality due to deferred care for acute medical conditions (e.g., exacerbation of heart failure, decompensated lower respiratory tract disease).

3. What is the established evidence or evaluation supporting proposed benefits, and the evaluation of potential harms of AI-driven solutions such as increased racial bias?

D. Public-Private Partnerships

1. Provide ideas of the form and function of a public-private partnership model to leverage the adoption of technology-driven solutions to improve outcomes for at-risk populations such as aging Americans living in rural areas.

2. What organizations, groups, and/or associations should HHS engage as part of such a collaborative effort?

HHS encourages all potentially interested parties—individuals, associations, governmental, non-governmental organizations, academic institutions, and private sector

entities—to respond. To facilitate review of the responses, please reference the question category and number in your response.

Dated: November 10, 2020.

Brett P. Giroir,

ADM, U.S. Public Health Service.

[FR Doc. 2020–25328 Filed 11–16–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. During this meeting, the TBDWG will finalize and vote on the 2020 report to the HHS Secretary and Congress. The agenda will be available on the website prior to the meeting. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; Federal activities related to tick-borne diseases; and gaps in tick-borne disease research.

DATES: The meeting will be held online via webcast on December 2, 2020, from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at <https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-12-2/index.html> when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC 20024. Email: tickbornedisease@hhs.gov; Phone: 202–795–7608.

SUPPLEMENTARY INFORMATION: Please register for the meeting at <https://events->